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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NGUYEN, BAO THUY L	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/845,736	JACKOWSKI ET AL.	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 April 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 36-43* is/are pending in the application.

4a) Of the above claim(s) *41-43* is/are withdrawn from consideration.

5)☒ Claim(s) *1* is/are allowed.

6)☒ Claim(s) *36-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The preliminary amendments dated 4/19/2002, 8/27,2002 and 10/27/2003 have been received.

2. Claims 1 and 36-43 are pending. Claims 2-35 have been canceled.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 36-40, drawn to a biopolymer marker having SEQ ID NO. 1 and method for using, classified in class 530, subclass 326, for example.

II. Claims 41-43, drawn to a diagnostic kit, classified in class 435, subclass 7.1, for example.

4. The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and contains different components. The antibody of Group II is not required in the method of group I.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because the

search required for Group I is not required for Group II restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Katherine Davies on May 31, 2005 a provisional election was made without traverse to prosecute the invention of Group I, claims 1 and 36-40. Affirmation of this election must be made by applicant in replying to this Office action. Claims 41-43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112, second paragraph

8. Claims 36-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36-40 are vague and indefinite with respect to the recitation in step c. It is unclear what criteria are used in comparing the mass spectrum profile of the detected sample to the mass spectrum profile of SEQ ID NO. Does this mean a 100% match? Is it the same to say that detection of SEQ ID NO. 1 in the patient sample is diagnostic for

myocardial infarction? If so, it is suggested that applicant amends the claims such as to clearly and concisely claim the invention.

The claims are also confusing because it is unclear what characteristics are used as the basis of comparison. These "characteristics" have not been clearly defined.

Claim Rejections - 35 USC § 112, first paragraph

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 36-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 36-40 recite a method for diagnosing congestive heart failure by detecting a biopolymer marker from a patient sample and comparing the detected biopolymer marker to the biopolymer marker having SEQ ID NO. 1. Recognition of a mass spectrum profile in the detected sample displaying the characteristic profile of the mass spectrum profile of SEQ ID No. 1 is diagnostic for congestive heart failure. Such a method is not supported by the specification.

The specification at pages 26-31 discloses how a biopolymer marker identified as SEQ ID NO. 1 was identified from patient serum samples, however, nowhere in the

specification is there is teaching of detecting any other biopolymer marker, comparing the detected marker to SEQ ID NO. 1, and determining a disease state from the detected marker. Furthermore, it is unclear what criteria are used in comparing the mass spectrum profile of the detected sample to the mass spectrum profile of SEQ ID NO. 1. The claim recites that recognition of a mass spectrum profile in the sample displaying the characteristic profile of mass spectrum profile for the peptide consisting of SEQ ID NO. 1 is diagnostic for congestive heart failure; however, there is no clear teaching of this in the specification or anywhere else how this is accomplished.

11. Claims 36-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

Claims 36-40 are directed to a method for diagnosing congestive heart failure by detecting at least one biopolymer marker from a patient sample and comparing the detected biopolymer to SEQ ID NO. 1. Recognition of a mass spectrum profile in the sample displaying the characteristic profile of the mass spectrum profile for SEQ ID NO. 1 is diagnostic for congestive heart failure. Such a method has not been describe in the specification in such a way as to enable one skill in the art to make and use the invention as claimed.

The specification states that a biopolymer marker having SEQ ID NO. 1 was found in serum samples of patients suffering from a variety of disease states (specification, page 26, lines 20-22) including congestive heart failure (specification, page 27, line 17 through page 28, line 2.) However, the specification does not have any data supporting this assertion. Data presented in Figure 1 is not convincing, nor does it clearly demonstrate that SEQ ID NO. 1 is indicative of congestive heart failure. The specification at page 26, line 20 teaches that serum samples from patients suffering from a variety of diseases were analyzed using protein chips and the profiles were analyzed to discern notable sequences that were deemed in some way evidentiary of at least one disease state. The specification goes on to say that the samples were concentrated by centrifugation and the filtrate was discarded and the retained solution, containing two peptides of interest, was analyzed by tandem mass spectrometry. As a result of these procedures the disease specific marker consisting of SEQ ID NO. 1 was found. The

specification asserts that from data set forth in Figure 1, this marker is indicative of congestive heart failure.

It is unclear how SEQ ID NO. 1 was identified as a "notable sequence" or how it was deemed "evidentiary" of a disease state. There is nothing specific in the procedure that would enable one to choose SEQ ID NO. 1 as a notable sequence among all other possible proteins or peptides present in the sample. There is no nexus between the procedure for screening samples from patients suspected of having a variety of different diseases, identifying SEQ ID NO. 1 as a disease marker, and determining that SEQ ID NO. 1 is diagnostic for congestive heart failure.

According to Strongin (1993, "Sensitivity, Specificity, and Predictive Value of Diagnostic Tests: Definitions and Clinical Applications", in Laboratory Diagnosis of Viral Infections, Lennette, e., ed., Marcel Dekker, Inc., New York, pp. 211-219) a number of characteristics need to be considered in the development of any suitable diagnostic assay. These characteristics include the following: (1) the sensitivity of the assay; (2) the true-positive test rate; (3) the false-negative test rate; (4) the specificity, or percentage of patients without the disease who will display a negative results; (5) the true-negative test rate; (6) the false-positive test rate; (7) the predictive value, or the probability that the test result is correctly indicating the presence or absence of the disease; (8) the prevalence, or number of patients in any given population that have the disease in question; (9) the efficiency or percentage of all results that are true; (10) the accuracy of the recited diagnostic assay. Additional considerations must also be examined to

enable the clinician to practice the invention including assessment of the following: (1) when is the maximum sensitivity desired?; (2) when is the maximum specificity desired?; (3) when is the maximum efficiency desired?; (4) How is the maximum sensitivity or specificity achieved?; (5) how is the predictive value maximized? An essential understanding of these factors is required to enable the skilled artisan to accurately use and interpret any given diagnostic test. Since the specification lacks any teaching of how the diagnostic tests were performed, or any information regarding the patients from which the samples were taken, and whether any considerations were given to any of the characteristics state above, it would require undue experimentation for one skilled in the art to make and use the invention as claimed.

The specification lacks proper guidance to enable one skill in the art to determine the incidence of disease as related to the presence or absence of a biopolymer that correspond to the maker having SEQ ID NO. 1. The specification further lack proper guidance to enable one skilled in the art to distinguish between any and all disease states as claimed.

Because of the lack of description in the specification for the claimed method, it cannot be conclusively determined from the data presented in Figure 1 that anyone or everyone who has this polypeptide marker suffers from any diseases, specifically congestive heart failure. Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966)

(stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001. That requirement has not been met in this specification with respect to a method for diagnosing congestive heart failure by detecting a biopolymer marker in a patient sample and comparing the detected biopolymer to a biopolymer marker having SEQ ID. NO. 1.

Therefore, it is maintained that one of ordinary skill in the art could not make and use the invention as claimed without undue experimentation.

Double Patenting

12. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

13. Claims 1, 36-40 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-6 of prior U.S. Patent No. 6,756,476 B2. This is a double patenting rejection.

The claims of the instant application and those of US 6,756,476 are both directed to an isolated biopolymer marker peptide consisting of SEQ ID NO. 1 (SSKITHRIHWESASLLR) and to a method for identifying said sequence in a sample using Mass Spec. Furthermore, they are both claiming the diagnoses of congestive heart failure by identifying the presence of SEQ ID NO. 1.

14. Claim 1 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of copending Application No. 09/846,346. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The claims of the instant application and those of 09/846,346 are both directed to an isolated biopolymer marker peptide consisting of SEQ ID NO. 1 (SSKITHRIHWESASLLR).

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 36-40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-40 of copending Application No. 09/846,346. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both claiming the identification of SEQ ID NO. 1 from a sample and relating said SEQ ID NO. 1 to a particular disease. Although the instant claims are drawn to the identification of congestive heart failure and the claims of '346 are drawn to the identification of type II diabetes, they are not seen to be different since the specification for both applications asserts that SEQ ID NO. 1 can be related to both diseases.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. -3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641
6/10/05